K071265

5.0 510(k) Summary

Submitted by:	Unipath Ltd Priory Business Park Bedford MK44 3UP UK +44 1234 835530 Contact Person: Lesley Moore
Date Prepared:	30th October 2007
Device Name:	SmartCheck INR™ System
Classification Name:	Multipurpose System for *in vitro* Coagulation Studies 21 CFR Part 864.5425
Predicate Device:	Roche Diagnostics Corporation CoaguChek® S System cleared under 510(k) Numbers k020831 and k994349.
Description:	The SmartCheck INR™ system consists of a hand held battery-powered meter with ROM calibration chip, disposable, dual-chambered, test strips and high and low level external liquid controls. When blood is applied to the strip it migrates by capillary action to the reaction chambers of the strip. The reaction chamber contains a metallic disc and rabbit brain thromboplastin reagent. When blood enters the reaction chamber a magnetic field is applied to the strip to activate disc movement. Upon clot formation, the disc becomes immobilized and clotting is optically detected. Clotting time is calculated and displayed as an INR value.
Intended Use:	The SmartCheck INR™ System is intended for quantitative testing of Prothrombin Time in capillary blood. Results are given in International Normalized Ratio (INR) units. The SmartCheck INR™ System is indicated for use by trained medical professionals in a point of care setting for monitoring the INR of patients on oral anticoagulant therapy.
Predicate Comparison:	The SmartCheck INR™ System and the predicate system both use a hand held meter and disposable strips for the determination of clotting time in capillary whole blood. The Systems have comparable test strip reagents and clot detection technology. Both use external liquid controls. The systems differ in the blood volume needed to carry out a test, the time to result, strip and ROMkey design, memory and meter specifications.

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Testing and Conclusion:	The SmartCheck INR™ System was evaluated for non-clinical and clinical performance. SmartCheck INR passed all tests and correlated favourably to a venous plasma based PT test with respect to accuracy and precision. A summary of the results is presented below for combined site calculations and support the conclusion that the SmartCheck INR™ System is substantially equivalent to the predicate CoaguChek S System.

Accuracy: SmartCheck INR Capillary Blood v. Venous Plasma INR ACL 10000 with recombinant thromboplastin (recTP), PTHS+ reagent and PT/Fibrinogen reagent (PT/Fib).

Parameter	recTP	PTHS+	PT/Fib
n	315	310	314
Regression Curve	y = 1.17x – 0.49	y = 1.48x – 1.19	y = 1.31x – 0.90
Correlation Coefficient	0.9235	0.9009	0.9036
Slope (95% CI)	1.17 (1.07 to 1.27)	1.48 (1.32 to 1.63)	1.31 (1.21 to 1.42)
Intercept (95% CI)	-0.49 (-0.73 to -0.25)	-1.19 (-1.57 to -0.81)	-0.90 (-1.16 to -0.65)
Range x	1.2 to 6.2	1.2 to 6.6	1.1 to 6.2
Range y	0.9 to 7.2	0.9 to 7.2	0.9 to 7.2
$S_{y,x}$	0.250	0.247	0.263
Mean Bias: Units or % (95% CI)	-0.045 or -1.7% -0.78 to 0.70	0.036 or 1.4% -0.87 to 0.94	-0.062 or -2.3% -0.91 to 0.79

Precision: SmartCheck INR Capillary Blood Measurement On Duplicate Finger Sticks

n	280
Mean INR	2.61
Standard Deviation	0.227
%CV	8.70

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Inverness Medical Innovations, Inc.
C/O Lesley Moore
51 Sawyer Road
Suite 200
Waltham, Massachusetts 02453

Re: k071265
Trade/Device Name: Smartcheck INR System
Regulation Number: 21 CFR 864.5425
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: JPA
Dated: May 3, 2007
Received: May 7, 2007

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

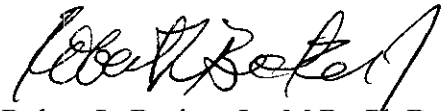
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071265

Device Name: The Inverness Medical Innovations, Inc. SmartCheck INR™ System

Indications For Use: The SmartCheck INR™ System is intended for quantitative testing of Prothrombin Time in capillary blood. Results are given in International Normalized Ratio (INR) units.

The SmartCheck INR System is indicated for use by trained medical professionals in a point of care setting for monitoring the INR of patients on oral anticoagulant therapy.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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